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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,260	07/22/2003	Philip J. Gotwals	A073-USCN2	4395

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,260	GOTWALS ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-22,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24* is/are allowed.

6)☒ Claim(s) *18-22 and 25* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/10/05, is acknowledged.

2. Claims 17-22 and 24-25 are pending.

3. Applicant's IDS, filed 12/10/04, is acknowledged. The JP-08131185 publication and the Pappadopoulos *et al* reference were considered only to the extent of their English abstracts.

4. In view of the amendment filed on 12/10/05, only the following rejection are remained.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18, 20, 22 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treatment or inhibiting rheumatoid arthritis comprising administering to a subject anti-α1-I domain antibody, does not reasonably provide **enablement** for a method for "preventing" of rheumatoid arthritis comprising administering to a subject at risk of developing or suffering from rheumatoid arthritis an anti-a1-I-domain blocking antibody, wherein the amino acid sequence of the antibody epitope comprises the sequence Val-Gln-Arg-Gly-Gly-Arg (SEQ ID NO: 8) in claim 22, or a method for "preventing" rheumatoid arthritis comprising administering to a subject at risk of developing or suffering for rheumatoid arthritis an antibody molecule comprising antigen binding regions derived from the light and heavy chain variable regions of an antibody to an a1b1 integrin, wherein the antibody is AJH10, which is secreted by a hybridoma designated as ATCC PTA-3580 in claim 25. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 6/17/04.

Applicant's arguments, filed 12/10/04, have been fully considered, but have not been found convincing.

Applicant has not address the issue regarding methods of "prevention" raised in the previous 4. office action mailed 6/17/05. Again, the Examiner reiterates the previous rejection:

On the basis of the disclosed correlation of the anti-fibrotic treatment and the tendency of reducing BL-induced lung collagen accumulation in mice observation alone, applicant concludes that the scope of the antibody against α1β1 encompassed by the claimed invention can have biological activity to prevent the RA and be provided as pharmaceutical compositions to subjects including human to effectively prevent RA. It is unclear which patients would be candidates for in vivo prevention with antibodies to α1β1 integrin. In addition, although such antibodies were

to reduce BL-induced lung collagen accumulation in mice, it is unclear if these assay results are predictive of a method for preventing RA comprising administering the antibody that immunoreacts with $\alpha 1\beta 1$.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 19-22 stand rejected under 35 U.S.C. 102(e2) as being anticipated by US. Pat. No. 5,855,888.

The `888 patent teaches a method for treating rheumatoid arthritis comprising administering to a patient an anti-VLA-1 ($\alpha 1\beta 1$) antibody (see col., 4-5 under Experiment 1, table 1 and patented claims 1-6 in particular). The `888 patent teaches that the antibody used for the RA treating drug can inhibit the swelling due to arthritis in RA, specially mAb that recognize the extracellular region of adhesion molecule of human VLA family (see col., 4, lines 39-46 in particular). The `888 patent further teaches that the antibody can be chimeric antibody (col., 3, lines 42-46), humanized antibody (col., 3, line 59) or monoclonal (see col., 4, lines 62-65). Furthermore, the patented anti-VLA-1 antibody recognizes an epitope on VLA-1 protein which comprises claimed SEQ ID NO: 8. The term "comprises" in claims 21-22 is open-ended so that the epitope may include additional amino acids on either or both of the N- or C- termini of given sequence.

The reference teachings anticipate the claimed invention.

Applicant's arguments, filed 12/10/04, have been fully considered, but have not been found convincing.

Applicant argues that the `888 patentees showed that a VLA-2 monoclonal antibody was around two times more effective than a VLA-1 monoclonal antibody (Sumitomo SE-A1013) inhibiting swelling in a murine rheumatoid arthritis model. Applicant further argues that the `888 patent did not disclose that the epitope of Sumitomo SE-A1013 comprised the amino acids of SEQ ID NO: 8 of the instant application. Applicant contends that the `888 patent fails to provide any information regarding the epitope of Sumitomo SE-A1013.

However the claim limitations are met by the prior art of the `888 patent irrespective of the effectiveness of the VLA-1 monoclonal antibody. Regarding the argument that the `888 patent did not disclose the epitope comprising the amino acid of SEQ ID NO:8, the Examiner notes that the antibodies which recognize the extracellular region of adhesion molecule of human VLA-1were effective to inhibit the swelling due to arthritis in RA. Therefore binding to said epitope is considered an inherent property of the reference antibody. Further, since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibody does not bind to said epitope comprising SEQ ID NO:8 recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

9. Claims 19-22 stand rejected under 35 U.S.C. 102(e2) as being anticipated by U.S. Patent No. 5,788,966.

The `966 patent teaches a method for treating arthritis (see the entire document and column 10, patented claims 1-8 and column 8 lines 65-67 in particular) such as rheumatoid arthritis (see col., 3 lines 64-65 in particular) that is associated with elevated levels of VLA-1 comprising administering to a human a monoclonal antibody 1B3.1 or a fragment thereto (column 3 lines 5-10) that inhibits collagen binding to VLA-1 (see entire document and reference claims 1-8, column 10 in particular). Furthermore, the `966 patent teaches that IB3.1 antibody recognizes an epitope on VLA-1 protein (see column 8 lines 39-46 in particular). The term "comprises" in claims 21-22 is open-ended so that the epitope may include additional amino acids on either or both of the N- or C- termini of given sequence.

The reference teachings anticipate the claimed invention.

Applicant's arguments, filed 12/10/04, have been fully considered, but have not been found convincing.

Applicant argues that the `966 patent did not disclose that mAb 1B3.1 bound to an epitope comprising SEQ ID NO: 8 of the instant application. Applicant submits that the `966 patent indicated that not all VLA-1 antibodies target the same epitope and stressed that mAb 1B3.1 bound to a different epitope than the known VLA-1 antibody TS2/7. Further, Applicant argues that the `966 patent does not disclose that the epitope of mAb 1B3.1 includes the amino acids of SEQ ID NO:8. Applicant submits that the fact that the epitope of the antibodies used in the methods claimed hereinis defined as comprising SEQ ID NO:8 does not mean that the epitope of those antibodies encompass the mAb 1B3.1 epitope. Applicant points to Kern et al for support that mAb 1B3.1 epitope does not encompass SEQ ID NO:8. Applicant submits that Kern analyzed the binding of mAb 1B3.1 to the α1 I-domain. Applicant argues that while the human a1 I-domain disclosed in Figure 2 of Kern includes the amino acid sequence of SEQ I DNO:8, kern did not specify that mAb 1B3.1 bound to an epitope within the human α1-I-domain which included the amino acid sequence of SEQ ID NO: 8.

However the claim limitations are met by the prior art of the '966 patent. Regarding IB3.1 antibody the examiner agrees with applicant analysis that mAb 1B2.1 binds to the α1-I-doamin which comprises SEQ ID NO: 8. Since Kern did not specify that mAB 1B3.1 bound to an epitope comprising SEQ ID NO: 8 it is Applicant's burden to show that the reference antibody does not bind to said epitope comprising SEQ ID NO: 8.

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibody does not bind to said epitope comprising SEQ ID NO:8 recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

10. The terminal disclaimer in conjunction with Applicant statement that 09/996,738 and the instant invention have at all times been commonly owned by or subject to an obligation of assignment to Biogen Idec, Inc. MA, Inc. or its predecessor corporation Biogen, Inc. obviate the rejection under the nonstatutory double patenting rejection.

11. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claim 24 is allowable.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
April 4, 2005

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